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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,926	06/01/2001	Bernard John Carroll	99977-410	1281

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,926	CARROLL, BERNARD JOHN	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-9,20 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-9,20 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed December 3, 2003 has been entered.

Claims 4, 10-19 and 21-22 are cancelled.

Claims 1-3, 5-9 and 20 are currently amended.

Claims 23-26 are newly added.

Claims 1-3, 5-9, 20 and 23-26 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-9, 20 and 23-26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record set forth in the office action mailed June 3, 2003.

Applicant's arguments filed December 3, 2003, have been fully considered but they are not persuasive.

Applicant argues that the claimed invention is sufficiently described because the functional properties of the PMGS of SEQ ID NO:1 are taught in the specification. Applicant points in particular to the specification (Examples 1 and 2, Figure 3) as elucidating a mode of action for the PMGS, to prevent or reduce silencing of a proximal nucleotide sequence by preventing or reducing methylation, or by promoting demethylation, of the proximal nucleotide

sequence. Applicant additionally points out that the claims as presently amended are supported by the specification (Examples 2 and 3; Figure 3) which teaches the tomato alpha amylase gene promoter PMGS of SEQ ID NO:1 (reply pages 18-19).

The Examiner maintains that the functional properties of SEQ ID NO:1 are not disclosed. Neither Examples 1 or 2, nor Figure 3, make any specific reference to a particular mode of action for SEQ ID NO:1. Example 1 explains the general properties of a Ds/Ac transposon system used to tag and clone tomato genes. Example 2 further explains the system, which is used to tag chromosomal regions that enable full expression of a *nos:BAR* transgene contained within the Ds element. Example 2 also explains that comparison of expressing and nonexpressing *nos:BAR* Ds lines by Southern hybridization indicates that silencing of *nos:BAR* expression is correlated with *nos:BAR* methylation. Example 2 does not describe specific sequences in the vicinity of the Ds insertion that affect the methylation status of the *nos:BAR* transgene contained within the Ds element, or the mechanism by which the methylation status of the *nos:BAR* transgene is affected. With respect to Example 3, Example 3 additionally explains the cloning of specific tomato sequences flanking the Ds transposon in the *nos:BAR* expressing line UQ406. Example 3 indicates the Ds element in line UQ406 has inserted into the promoter region of an alpha amylase gene, and the promoter region is identified as SEQ ID NO:1. Example 3 does not describe which of the specific sequences flanking the Ds transposon in the *nos:BAR* expressing line UQ406, if any, affects the methylation status of the *nos:BAR* transgene, or the mechanism by which the methylation status is affected. Example 3 also does not describe which of the nucleotides of SEQ ID NO:1 drive the transcription of the native tomato alpha amylase gene, or whether SEQ ID

NO:1 functions to drive the transcription of a heterologous coding sequence operably linked thereto.

Claims 1-3, 5-9, 20 and 23-26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons of record set forth in the office action mailed June 3, 2003.

Applicant's arguments filed December 3, 2003, have been fully considered but they are not persuasive.

Applicant points out that a single enabled use is sufficient to satisfy the requirements of 35 USC 112, 1st paragraph, and argues this requirement is satisfied because the function of the PMGS of SEQ ID NO:1 is demonstrated by the expression of a *nos:BAR* transgene contained within a Ds element inserted into the PMGS of SEQ ID NO:1, said transgene expression being correlated with hypomethylation of the *nos* promoter. Applicant also argues that specification additionally teaches that the PMGS of SEQ ID NO:1 could be used to stabilize or initiate the expression of other nucleic acid sequences. Applicant further argues that amendment of the claims to recite that the claimed sequence has at least 80% sequence similarity to SEQ ID NO:1 as opposed to at least 25% sequence similarity to SEQ ID NO:1would be reasonably expected by one skilled in the art to have a function similar to that disclosed for the claimed PMGS. Applicant also points out that the testing of sequences for promoter function was routine in the art at the time of filing, and that the use of promoters to express heterologous sequences operably linked thereto was also routine in the art at the time of filing. Applicant argues that in light of the

state of the art it would require only routine experimentation to make and test an expression construct comprising SEQ ID NO:1. (reply pages 20-22).

The Examiner maintains that no use for SEQ ID NO:1 has been established. That the nucleotides of SEQ ID NO:1 flank an active *nos:BAR* transgene having a hypomethylated *nos* promoter in the genome of a transposon tagged line does not demonstrate that the nucleotides of SEQ ID NO:1 are in any way responsible for the hypomethylation of the *nos* promoter of the *nos:BAR* transgene, as many other nucleotides and/or proteins in the vicinity of the *nos:BAR* transgene could also account for its hypomethylation. Furthermore, that the nucleotide sequence of SEQ ID NO:1 is located upstream of a tomato alpha amylase coding sequence does not demonstrate that an isolated nucleotide sequence of SEQ ID NO:1 has promoter function, as the isolated nucleotide sequence of SEQ ID NO:1 may not contain all of the specific nucleotides required to drive the transcription of the native tomato alpha amylase coding sequence in planta, or sufficient specific nucleotides required to drive the transcription of a heterologous sequence operably linked thereto. Furthermore, while one skilled in the art could readily test an expression construct comprising SEQ ID NO:1 for promoter function, it is unpredictable whether SEQ ID NO:1 or any sequence having at least 80% sequence similarity to SEQ ID NO:1 or any sequence capable of hybridizing to SEQ ID NO:1, would have a promoter function, as Applicant has not provided guidance with respect to which nucleotides of SEQ ID NO:1, if any, mediate promoter function.

Claims 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulates" expression, for the reasons of record set forth in the office action mailed June 3, 2003.

Applicant's arguments filed December 3, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn because the term "modulates" is used and understood by those skilled in the art to indicate changes that influence or affect a function or activity, such as by increasing, enhancing, decreasing, inhibiting or stabilizing a function or activity. Applicant also points out that the term is described in the specification in connection with the expression of the alpha amylase gene, as increasing or stabilizing or decreasing or inhibiting alpha amylase gene expression (reply page 23).

The rejection is maintained because the varied use of the term "modulates" by those skilled in the art and in the specification does not limit or clarify the meaning of the term "modulates" in the rejected claim.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the recited conditions would constitute "medium" stringency conditions, as the recited conditions omit the hybridization temperature.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. It is unclear whether the recited conditions would constitute "high" stringency conditions, as the recited conditions omit the hybridization temperature.

Claim Rejections - 35 USC § 102

Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/12813 (published 02 May 1996, Applicant's IDS).

The claims are drawn to sequence capable of hybridizing to the PMGS according to claim 1 or claim 20 under medium or high stringency conditions.

WO 96/12813 teaches a potato alpha amylase promoter sequence (Figure 4). The potato alpha amylase promoter sequence would be capable of hybridizing to the PMGS according to claim 1 or claim 20 under medium or high stringency conditions because the sequence has a high degree (77.5%) of sequence similarity to SEQ ID NO:1, and because Applicants own specification indicates that SEQ ID NO:1 shows strong similarity to the potato alpha amylase promoter (page 28 lines 15-16; Figure 4). Applicant's arguments filed December 3, 2003, in response to the previous rejection (now withdrawn) of claims 1, 3-9 and 20-21 under 35 U.S.C. 102(b) as being anticipated by WO 96/12813 are not germane to the instant rejection as the previously rejected claims were not drawn to hybridizing sequences.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Claims 1-3, 5-9, 20 and 25-26 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleotide sequence of SEQ ID NO:1, or a sequence having at least 80% similarity thereto.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CC
February 5, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~160~~ 1638